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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,022	03/22/2004	Jeffrey S. Kiel	455-024	1967

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EXAMINER	
OH, TAYLOR V	
ART UNIT	**PAPER NUMBER**
1625	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,022	KIEL ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's arguments with respect to claims 1-2 and 5-21 have been considered but are moot in view of the new ground(s) of rejection.

The Status of Claims

Claims 1-2 and 5-21 are pending.

Claims 1-2 and 5-21 are rejected.

DETAILED ACTION

1. Claims 1-2 and 5-21 are under consideration in this Office Action.

Priority

2. It is noted that this application claims benefit of 60/457,399 (03/25/03).

Drawings

3. None.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-2 and 5-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17, and 19-29 of copending Application No. 10/806,260. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 5-6 are related to the process for preparing a gabapentin tannate by reacting gabapentin with tannic acid to produce gabapentin tannate , whereas the claim 1 of the copending Application No. 10/806,260 is for the process for preparing a gabapentin tannate composition for treating a condition of the central nervous system in an mammalian subject by reacting gabapentin with tannic acid to produce a pharmaceutically effective amount of gabapentin tannate .

However, the prior art differs from in the instant invention that the phrase "for treating a condition of the central nervous system in an mammalian subject " is incorporated into the process claims.

Even so, the specification describes that it is possible to conduct the process for preparing a gabapentin tannate by reacting gabapentin with tannic acid to produce gabapentin tannate without mentioning the treatment of a condition of the central nervous system in an mammalian subject administering a pharmaceutically effective amount of gabapentin tannate. Therefore, it would have been obvious to the skillful artisan in the art to be motivated to remove those limitations in the claims in such a way to emphasize the certain aspect of the processing claimed invention because

they are not patentably distinct from each other with respect to the claims of themselves.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-2,5-10,12,14, and 18-19 provisionally are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 10/805,806. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 5-6 is for the method of synthesizing gabapentin tannate by mixing gabapentin with tannic acid to obtain gabapentin tannate wherein the tannic acid component is of either natural or synthetic origin.
, whereas the claims 1-16 of the copending Application No. 10805,806 are for the process for preparing a gabapentin tannate by reacting gabapentin with tannic acid to produce a pharmaceutically effective amount of gabapentin tannate in solid dosage form wherein the tannic acid component is of either natural or synthetic origin

However, the instant invention differs from the prior art in that the usage difference of the weight of tannic acid and gabapentin is described in a ratio rather than a proportion in the claim.

Even so, concerning their respective range of tannic acid and gabapentin between them , they are overlapped with each other. Therefore, it would have been obvious to the skillful artisan in the art to be motivated to use the ratio instead of the proportion in the claims because they are not patentably distinct from each other with respect to the claims of themselves.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2 and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryans et al (US 7,141,606) in view of Berge et al (J. of Pharmaceutical Sciences, 66,no. 1, Jan, 1977, p.1-19).

Bryans et al discloses gabapentin derivatives for sleep disorders (see an abstract page). Furthermore, the gabapentin has a nitrogen and a carboxyl group in the chemical compound and its salt possible forms are described in the followings (see col. 10 ,lines 33-37):

> Since amino acids are amphoteric, pharmacologically compatible salts when R is hydrogen can be salts of appropriate inorganic or organic acids, for example, hydrochloric, sulphuric, phosphoric, acetic, oxalic, lactic, citric, malic, salicylic, malonic, maleic, succinic, methanesulfonic acid,

However, the instant invention differs from the prior art in that the formation of gabapentin tannate is undisclosed in the prior art.

Berge et al describes potentially useful salts in the pharmaceutical compounds in which the salt is formed by an acid-base reaction involving either a proton-transfer or neutralization reaction (see page 2 , left col. at the middle paragraph). Furthermore the table I shows various FDA-approved commercially marketed salts among which the tannate is displayed as one of the potential candidates for the pharmaceutical compounds.

Bryans et al expressly discloses that it seems reasonable to form the organic salt forms of gabapentin for sleep disorders (see col. 10 ,lines 33-37). Berge et al expressly describes various FDA-approved commercially marketed salts among which the tannate is displayed as one of the potential candidates for the pharmaceutical compounds. Therefore, it would have been obvious to the skillful artisan in the art to be motivated to use the tannate for the salt of gabapentin for sleep disorders ; this is because Berge et al expressly teaches that one of the FDA-approved commercially marketed salts can be the tannate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taylor Victor Oh, MSD,LAC
Primary Examiner
Art Unit : 1625

*** 4/11/07